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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,181	02/26/2004	Charles R. Mooney	ECC-5062CIP2DIV	6985
30452 7590 02/26/2009 EDWARDS LIFESCIENCES CORPORATION LEGAL DEPARTMENT ONE EDWARDS WAY IRVINE, CA 92614				
EXAMINER VU, QUYNH-NHU HOANG				
ART UNIT		PAPER NUMBER		
3763				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/789,181

Applicant(s)

MOONEY ET AL.

Examiner

QUYNH-NHU H. VU

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 13, 14, 17, 18 and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-12, 15-16, 19-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-540)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/24/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

Amendment and Request for Continued Examination (RCE) filed on 12/19/08 has been entered.

Claims 1-5, 9-12, 1516, 19-20 are present for examination.

Claims 6-8, 13-14, 17-18, 21-26 are withdrawn.

### *Drawings*

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitation "a side arm opening immediately downstream with respect to the hemostasis valve" and the limitation "the introducer is converted from an infusion introducer to a multiple lumen access device by virtue of the main channel and the auxiliary channel in the junction housing" of claims 1 and 15 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "a side arm opening immediately downstream with respect to the hemostasis valve" is vague and unclear. Does Applicant mean the side arm opening located below the hemostasis valve?

The limitation: "the introducer is converted from an infusion introducer to a multiple lumen access device by virtue of the main channel and the auxiliary channel in the junction housing" is vague and unclear. Examiner requests Applicant explain more details that how is introducer converted from an infusion introducer to a multiple lumen access device by virtue of the main channel and the auxiliary channel in the junction housing?

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9-12, 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz et al. (US 5,156,596) in view of Nishijima et al. (US 5,092,846) or Bacich et al. (US 5,749,889).

As best as understood, Balbierz discloses a multiple lumen access device comprising: an infusion introducer 28 having an access tube with a proximal end and a distal end for introduction into the body; the introducer 28 including a hub 22 connected to the proximal end of the access tube, a valve 70 in a fixed location within the hub that provides a seal around medical implements that are introduced and withdrawn to and from the body through an access tube lumen;

a catheter 28, 52 (Figs. 1-12) including a catheter tube and a junction housing 38 on a proximal end of the catheter tube, the junction housing 38 including a main channel 60 and at least one auxiliary channel 90, 92 separate from the main channel (Fig. 12); the main channel and the auxiliary channel being in fluid communication through the openings 93, 95 (Fig. 12);

a multi-function adapter (including portion of element 24 and element 66) having a first unit and second unit, the first unit being attached to the junction housing 38, and the second unit 24 (proximal portion of hub 22) being fixedly attached to the hub 22 (see Figs. 3-5); wherein the first unit (portion of element 66) maybe removably connected to the second unit.

Additionally, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. the first unit may be removably connected to the second unit such that the introducer is converted from an infusion introducer to a multiple lumen access device by virtue of the main channel and the auxiliary channel in the junction housing, a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974)

Balbierz does not disclose the introducer further including a side arm opening distally with respect to the valve.

Nishijima discloses that an introducer including a side arm 8 opening immediately downstream with respect to a valve 3 for infusing a medical solution to the access tube lumen (Figs. 1-7).

Bacich et al. discloses that an introducer including a side arm 106, 108 opening immediately downstream with respect to a valve 166, 168 for infusing a medical solution to the access tube lumen (Fig.6).

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Balbierz with a side arm, as taught by Nishijima or Bacich, in order to infuse/deliver the drug. Furthermore, the side arm provided and attached into the hub is very well-known in the art for intended use such as infuse/deliver drugs.

Regarding claim 5, Balbierz in view of Nishijima disclose the claimed invention except for the multi-function adapter comprises two L-shaped channels. However, it is well-known in the art to provide L-shaped channels, for example: Figs. 4-7 (different embodiment of Balbierz). Furthermore, it would have been an obvious matter of design choice to L-shaped channels, it appears that the invention would perform equally well with V-shaped or other shaped channels.

#### *Response to Arguments*

Applicant's arguments filed 12/19/08 have been fully considered but they are not persuasive.

1. Applicant argues that Balbierz does not teach a side arm opening distally with respect to the valve; Nishijima does not teach or suggest the multi-function adapter.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Balbierz does not disclose the side arm but Nishijima fully discloses the side arm structure same as claimed of invention. Nishijima does not teach the multi-function adapter but Balbierz fully disclose the multi-function adapter as discussed in the rejection above.

2. Applicant argues that there is no fluid communication between the lumen of the inner and outer cannula in the device of Balbierz.

In response, there is a fluid communication between the lumen 90/92 of the inner cannula and outer lumen 60 of outer cannula through the opening 93, 95 (Fig. 12).

#### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu  
Examiner  
Art Unit 3763